conversation with the Examiner on April 24, 2003. As required, Applicants now affirm the election of the claims of Group I.

The Office Action indicates that "[b]ecause applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse." With respect, telephone election practice allows applicants to provisionally elect a group of claims for examination with traverse and to point out the errors in the restriction requirement in their response to the office action following the telephone election. If this were not the case, applicants and examiners would be burdened with conducting substantive telephone interviews regarding the basis for traversal in which a less extensive record of the traversal might result. Further, if the substance of the traversal were required to be presented during the telephone call where the election is made, it is unlikely the applicants would ever agree to elect by telephone. In any case, Applicants assert that they are allowed to point out the errors in the restriction requirement in this Response and the Examiner must reconsider the restriction requirement in light of Applicants' assertions (MPEP § 821.01).

Applicants traverse the restriction requirement as currently set forth for the following reasons. To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. Applicants note that the restriction requirement does not provide any basis to indicate that examination of kit claims along with the method claims would overly burden the Examiner. The Office Action provides no reasons why it would be a burden. In fact, all of the components of the kit claims are explicitly recited and used in the claimed method. For this reason, the Examiner will be required to search and examine such

components while conducting a proper examination of the method claims. For all of these reasons, Applicants submit that the present restriction requirement is improper and request rejoinder and examination of all of the claims.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 1-136 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

It was alleged in the Office Action that the terms "reporter binding molecules" and "specific binding molecules" are indefinite and unclear "because it is not clear whether these binding molecules refer to primers or probes or peptides or peptide nucleic acids or any chemical compound." Applicants submit that both these terms are clear and definite when read in light of the specification. Both of these terms are clearly defined in the specification. Reporter binding molecules are defined and described at least from page 16, line 1, to page 19, line 16 (see especially page 16, lines 2-4). Specific binding molecules are defined and described at least on page 18, lines 22-31. Because Applicants are allowed to be their own lexicographer and because these terms are specifically defined in the specification, Applicants submit that both the terms and the claims in which they appear are clear and definite.

Rejection Under 35 U.S.C. § 102

Claims 1, 12-113 and 118-136 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kingsmore et al. (U.S. Pat. No. 6,531,283). Applicants respectfully traverse this rejection.

Kingsmore et al. discloses a method for detecting analytes involving bringing analytes into contact with reporter binding primers, which are made up of a specific binding molecule and

a rolling circle replication primer, such that the specific binding molecule binds to the analyte. An amplification target circle is brought into contact with the rolling circle replication primer (which is part of the reporter binding primer) and the amplification target circle is replicated via priming by the rolling circle replication primer, thus forming tandem sequence DNA. Kingsmore et al. fails to disclose decoupling of the amplification target circle from the reporter binding primers. In fact, in the method of Kingsmore et al. the amplification target circle is associated with the reporter binding primer (via the rolling circle replication primer) prior to replication and remains associated with the reporter binding primer during replication.

Applicants are claiming a method of detecting analytes that involves, *inter alia*, association of reporter binding molecules (which each comprise a specific binding and an amplification target circle) with analytes. The amplification target circles are replicated to produce tandem sequence DNA. Significantly, however, the amplification target circles are decoupled from the reporter binding molecules prior to replication (see step (b) of claim 1; step (c) of claims 107, 108, and 110; lines 8-9 of claims 124 and 133; lines 12-13 of claim 134; lines 10-11 of claim 135; and lines 13-14 of claim 136). At least because Kingsmore et al. fails to disclose decoupling of the amplification target circle from the reporter binding primers, Kingsmore et al. fails to disclose every feature of the claimed method. Accordingly, Kingsmore et al. fails to anticipate claims 1, 12-113 and 118-136.

Rejection Under 35 U.S.C. § 103

Claims 2-11 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kingsmore et al. (U.S. Pat. No. 6,531,283), in view of Lizardi et al. (U.S. Pat. No. 6,403,319). Applicants respectfully traverse this rejection.

Kingsmore et al. discloses a method for detecting analytes involving bringing analytes into contact with reporter binding primers, which are made up of a specific binding molecule and a rolling circle replication primer, such that the specific binding molecule binds to the analyte. An amplification target circle is brought into contact with the rolling circle replication primer (which is part of the reporter binding primer) and the amplification target circle is replicated via priming by the rolling circle replication primer, thus forming tandem sequence DNA. Kingsmore et al. fails to disclose or suggest decoupling of the amplification target circle from the reporter binding primers. In fact, in the method of Kingsmore et al. the amplification target circle is associated with the reporter binding primer (via the rolling circle replication primer) prior to replication and remains associated with the reporter binding primer during replication.

Lizardi et al. discloses a method of analyzing nucleic acid sequences by amplifying nucleic acids with primers able to form a hairpin structure. The hairpin structure (which forms in the amplified nucleic acid strands) allows the amplified nucleic acid strands to be covalently coupled to probes in an array. The probes in the array can interact with the amplified nucleic acid strands via base pairing. Lizardi et al. fails to disclose or suggest an amplification target circle that is part of a reporter molecule of any sort. Lizardi et al. also fails to disclose or suggest decoupling of an amplification target circle from any molecule or component.

Applicants are claiming a method of detecting analytes that involves, *inter alia*, association of reporter binding molecules (which each comprise a specific binding and an amplification target circle) with analytes. The amplification target circles are replicated to produce tandem sequence DNA. Significantly, however, the amplification target circles are decoupled from the reporter binding molecules prior to replication (see step (b) of claim 1, from

which claims 2-11 depend). Neither Kingsmore et al. nor Lizardi et al. disclose or suggest decoupling of an amplification target circle from a reporter binding primer, reporter binding molecule or any other component. At least because Kingsmore et al. and Lizardi et al. fail to disclose or suggest decoupling of an amplification target circle from a reporter binding primer, Kingsmore et al. and Lizardi et al. fail to disclose or suggest every feature of the claimed method. Accordingly, Kingsmore et al. and Lizardi et al., either alone or in combination, fail to make obvious claims 2-11.

Double Patenting Rejection

Claims 1, 12-113 and 118-136 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 6,531,283 to Kingsmore et al. Applicants respectfully traverse this rejection.

Claims 1-72 of U.S. Patent No. 6,531,283 (the '283 patent) encompass methods of analyte detection that involve, *inter alia*, bringing analytes into contact with reporter binding primers, which are made up of a specific binding molecule and a rolling circle replication primer, such that the specific binding molecule binds to the analyte. An amplification target circle is brought into contact with the rolling circle replication primer (which is part of the reporter binding primer) and the amplification target circle is replicated via priming by the rolling circle replication primer, thus forming tandem sequence DNA. None of the claims of the '283 patent recite that the amplification target circle is decoupled from the reporter binding primers. In fact, the amplification target circle is associated with the reporter binding primer (via the rolling circle replication primer) prior to replication and remains associated with the reporter binding primer during replication.

The Office Action asserts that the decoupling step "is an obvious variation to the step of separating analyte-capture agents from the analyte samples disclosed in the patented claims as discussed in the above rejection." First, nowhere does the Office Action make the case that decoupling of an amplification target circle from a reporter binding primer is an obvious variation of the process of separating an analyte capture agent from an analyte sample. In the '283 patent, analyte capture agents "allow the analyte to be immobilized or separated from other compounds and analytes." On the other hand, decoupling the amplification target from the reporter binding as presently claimed is used to free the amplification target circle for subsequent amplification. In fact, present claim 1 recites both the separation of "the specific binding molecules that interact with the analytes from the specific binding molecules that do not interact with the analytes" and the "decoupling the amplification target circles from the reporter binding molecule." Thus, these operations are not alternatives of the same process; rather, they are different, distinct processes. They are neither physically nor conceptually similar or analogous. In fact, the method of the '283 patent requires that the amplification target circle remain associated with the reporter binding primer since the reporter binding primer includes the rolling circle replication primer the method uses to replicate the amplification target circle. For all of these reasons, the presently claimed decoupling of amplification target circles from reporter binding molecules is not an obvious variation of any step or operation in the claims of the '283 patent. For at least these reasons, present claims 1, 12-113 and 118-136 are not obvious variations of claims 1-72 of the '283 patent. Accordingly, the present rejection cannot be sustained.

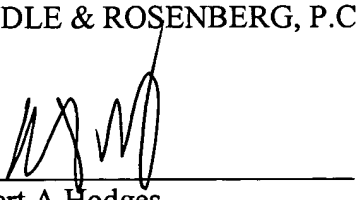
Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of $475.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(3), and a Request for Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

It is believed that no fee is due with this submission. However, the Commissioner is hereby authorized to charge any fees which may be required to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.



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I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as Express Mail, Label No. EL 992 076 841 US, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Michael Laird

11/10/03
Date